

**AMENDMENT UNDER 37 C.F.R. § 1.116**

**U.S. Appln. No. 10/553,639**

**(Attorney Docket No. Q90948)**

**REMARKS**

Claims 1, 5, 8-9, 12 and 32-36 are all the claims pending in the application. Claims 2-4 and 6-7 are canceled. Claims 10-11, 13-14 and 24-31 are withdrawn from consideration.

Claims 1, 5, 8-9, 12 and 32-36 are rejected. Claim 37 is new. Claims 1, 8 and 32-33 are amended herewith. Exemplary support for such amendments and new Claim 37 may be found throughout the specification, at for example, pages 34-37 of the specification and at for example, Figure 6. The amendments to Claims 8 and 32-33 are grammatical in nature.

No new matter is added by way of this amendment. Entry and consideration of this amendment are respectfully requested.

**I. Claim Objections**

On pages 2 to 3 of the Office Action, the Examiner objects to Claims 1, 8, 32 and 33 for the following reasons:

(1) With respect to Claim 1, line 4, the Examiner states that the phrase “each of said repeats has a complete nucleotide sequence”, should be amended for grammatical reasons to recite “each of said repeats having a complete nucleotide sequence”;

(2) Further with respect to Claim 1, the Examiner states that part (6) is allegedly confusing and contains functional limitations which adds very little structure to the claimed vector. The Examiner recommends deleting or amending part (6) of claim 1;

(3) With respect to Claim 8, line 3, the Examiner recommends amending the limitation “gene deletion site is *SwaI* recognition,” to “gene deletion site is a *SwaI* recognition” for grammatical reasons;

**AMENDMENT UNDER 37 C.F.R. § 1.116**

**U.S. Appln. No. 10/553,639**

**(Attorney Docket No. Q90948)**

(4) Claim 32, lines 2-3, is objected to because according to the Examiner “recognition sequences *is* *Sall* recognition or *NruI* recognition sequence”, should be amended for grammatical purposes to “recognition sequences are *Sall* or *NruI* recognition sequences;” and

(5) Claim 33, line 2, is objected to because according to the Examiner, “restriction enzyme recognition sequence which *is* not *present* in the”, should be amended for grammatically and typographical reasons to “restriction enzyme recognition sequences which are not present in the adenoviral genome,” and requires appropriate correction thereof.

Regarding the Examiner’s first basis of rejection, Claim 1, line 4 is herewith amended as recommended by the Examiner to recite “each of said repeats having a complete nucleotide sequence.” Withdrawal of the objection is respectfully requested.

Regarding the Examiner’s second basis of objection, we note that under U.S. practice, a functional limitation is an attempt to define something by what it does, rather than by what it is. A functional limitation is often used in association with an element, ingredient, or step of a process to define a particular capability or purpose that is served by the recited element, ingredient or step. See MPEP 2173.05. There is nothing inherently wrong with defining some part of an invention in functional terms. Functional language does not, in and of itself, render a claim improper. See *In re Swinehart*, 439 F.2d 210, 169 USPQ 226 (CCPA 1971).

Nevertheless, Applicants herewith amend Claim 1 to recites structural limitations in the cosmid vector, without reciting any intended use or functional limitations. Claim 1, as amended recites the structural components of the vector including adenoviral genome, the number and placement of the restriction enzyme recognition sequences and the drug resistant gene, a replication origin,

**AMENDMENT UNDER 37 C.F.R. § 1.116**

**U.S. Appln. No. 10/553,639**

**(Attorney Docket No. Q90948)**

a spacer sequence and a COS region. Applicants submit that Claim 1, as amended is sufficiently clear and respectfully request withdrawal of the claim objection.

Regarding the Examiner's third, fourth and fifth basis of rejection, Applicants have amended the claims as recommended by the Examiner for grammatical purposes. In particular, Claim 8, line 3, has been amended to recite a "gene deletion site is a *SwaI* recognition." Claim 32, lines 2-3 has been amended to recite "recognition sequences are *Sall* or *NruI* recognition sequences;" and Claim 33 , line 2, has been amended to recite a "restriction enzyme recognition sequences which are not present in the adenoviral genome." The claims, as amended, are sufficiently clear and Applicants respectfully request withdrawal of the objections.

**II. Rejection under 35 U.S.C. § 112**

On pages 3 to 4 of the Office Action, the Examiner rejects Claims 1, 5, 8, 9, 12 and 32-36 under 35 U.S.C. § 112, second paragraph, allegedly as being indefinite for the following reasons:

(1) With respect to Claim 1, the Examiner states that the claim is allegedly confusing because part (3) of the claim recites two "pairs" of identical restriction enzyme recognition sequences (restriction sites) and these pairs are located "on both sides of the adenoviral genome." The Examiner states that this causes confusion as to how many restriction sites are required to meet the claim limitations. The Examiner further states that recitation of a "second pair" of identical sites in part (5) causes confusion because it is allegedly unclear where in the vector one of these sites must be. The examiner concludes that the number and placement of the recited pairs of identical restriction sites cannot be determined from the claims, rendering the scope of the claimed subject matter unclear;

**AMENDMENT UNDER 37 C.F.R. § 1.116**

**U.S. Appln. No. 10/553,639**

**(Attorney Docket No. Q90948)**

(2) The Examiner further states that there is no antecedent basis for “a foreign gene” in part (2) of Claim 1 since the claim does not require insertion of a foreign gene and thus merely recites an intended use of the restriction site;

(3) Finally, the Examiner state that phrase “within the right side is a IVa2 gene side” in Claim 1 is allegedly confusing. In particular, the Examiner is confused as to the meaning of the “gene side.”

Initially, Claim 1 is herewith amended to recite, *inter alia*, a restriction enzyme recognition sequence in part (2), a first pair of identical restriction enzyme recognition sequences, wherein the first pair of sequences are not naturally present in the adenoviral genome, one of said sequences in the first pair is located on the left side of the left-inverted terminal repeat and the other of said sequences in the first pair is located on the right side of the right-inverted terminal repeat; a second pair of identical restriction enzyme recognition sequences, wherein one of the sequences in the second pair is located inside the E1 gene deletion site and at a right side of the restriction enzyme recognition sequence in (2), and the other of said sequences in the second pair is present inside the spacer sequence. Exemplary support for such amendments may be found throughout the specification, at for example pages 34-37 of the specification and at for example figure 6.

Applicants respectfully traverse and submit that Claim 1, as amended is sufficiently clear and definite. “The test for definiteness under 35 U.S.C. § 112, second paragraph is whether ‘those skilled in the art would understand what is claimed when the claim is read in light of the specification.’” MPEP § 2173.02 (citing *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986)). Further, the

**AMENDMENT UNDER 37 C.F.R. § 1.116**

**U.S. Appln. No. 10/553,639**

**(Attorney Docket No. Q90948)**

MPEP clearly states that “[d]efiniteness of claim language must be analyzed, not in a vacuum, but in light of (A) The content of the particular application disclosure; (B) The teachings of the prior art; and (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.” MPEP § 2173.02.

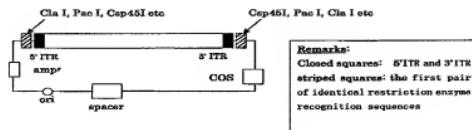
The cosmid vector as claimed and as described in the specification comprises at least five restriction enzyme recognition sequences. In particular, the cosmid vector comprises a restriction enzyme recognition sequence in the part (2) of claim 1, which is located in the E1 gene deletion site and wherein a foreign gene is inserted, a first pair of identical restriction enzyme recognition sequences, one of the restriction enzyme recognition sequences in the first pair is located on the left side of the left-inverted terminal repeat (ITR) of the adenoviral genome and the other restriction enzyme recognition sequence in the first pair is located at the right side of the right ITR. The cosmid vector, as claimed, also recites a second pair of identical restriction enzyme recognition sequences, one of the sequences in the second pair is located inside the E1 gene deletion site and at a right side of the restriction enzyme recognition sequence in (2), and the other of said sequences in the second pair is present inside the spacer sequence.

With regard to the first pair of restriction enzyme recognition sequences, the present specification at page 26, lines 17 to 25, describes that a cosmid vector comprising a first pair of identical restriction enzyme recognition sequences “can be easily and completely digested with the restriction enzyme” to enable the production of an adenoviral vector which is transformed into cells to incorporate thereto a foreign gene. Further, the illustration below is an exemplary figure which shows the first pair of restriction enzyme recognition sequences:

AMENDMENT UNDER 37 C.F.R. § 1.116

U.S. Appln. No. 10/553,639

(Attorney Docket No. Q90948)



As shown in the exemplary figure<sup>1</sup> above, the first pair of restriction enzyme recognition sequences which are labeled as for example, ClaI, PacI, and Csp45I, are located at the left side of the left ITR and the other of the identical restriction enzyme recognition sequence in the first pair of located at the right side of the right ITR.

Regarding the second pair of identical restriction enzyme recognition sequences, the claims as amended clearly set forth that one of the identical restriction enzyme recognition sequences in the second pair is located within the E1 gene deletion site and at a right side of the restriction enzyme recognition sequence in part (2) wherein a foreign gene is inserted, and the other restriction enzyme recognition sequence in the second pair is present inside the spacer sequence. Support for the claim, as amended, may be found, at for example, Figure 6; see also page 25, line 16 to page 26, line 4. Further, Applicants provide an exemplary illustration of the placement of the second pair of identical restriction enzyme recognition sequences below:

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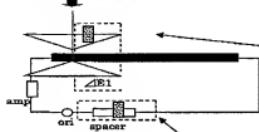
<sup>1</sup> The figures shown are for illustrative purposes only and are not intended to limit the claims. If the Examiner would prefer colored copies of the illustration, Applicants would be happy to provide such copies.

AMENDMENT UNDER 37 C.F.R. § 1.116

U.S. Appln. No. 10/553,639

(Attorney Docket No. Q90948)

the restriction enzyme recognition sequence (recognized by *Swa*I etc) wherein a foreign gene can be inserted is located in the *E1* gene deletion site.



Remarks

Dotted squares : the second pair of identical restriction enzyme recognition sequences.  
Closed square : the adenoviral genome.

One of the identical restriction enzyme recognition sequences in the second pair (recognized by *Sal*I, *Nru*I etc) is located in the *E1* gene deletion site and at the right side of the restriction enzyme recognition sequence (recognized by *Swa*I etc), wherein a foreign gene can be inserted, in the *E1* gene deletion site indicated by a dot line.

The other of the identical restriction enzyme recognition sequences in the second pair is located inside the spacer sequence indicated by a dot line.

As shown above, for illustrative purposes only, the second pair of identical restriction enzyme recognition sequences (recognized by *Sal*I, *Nru*I, etc) is located in the *E1* genome deletion site and at the right side of the restriction enzyme recognition sequence and the other of the identical restriction enzyme recognition sequences in the second pair is located in the spacer sequence. The claim, as amended, clearly sets forth that the number and placement of the recited pairs of identical restriction sites.

Regarding the Examiner's second basis of rejection, Claim 1, as amended recites, *inter alia*, a deletion in an adenovirus *E1* gene region wherein a "foreign gene is inserted." Thus, Claim 1 recites structural limitations and not merely intended use of the restriction site. Regarding the Examiner's third basis of rejection, the limitation "within the right side is a *IVa2* gene side" is deleted, rendering the rejection moot.

Applicants respectfully request withdrawal of the rejections.

**AMENDMENT UNDER 37 C.F.R. § 1.116**

**U.S. Appln. No. 10/553,639**

**(Attorney Docket No. Q90948)**

**Conclusion**

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The U.S. Patent and Trademark Office is hereby directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



Azy S. Kokabi

Registration No. 58,902

**SUGHRUE MION, PLLC**  
Telephone: (202) 293-7060  
Facsimile: (202) 293-7860

WASHINGTON OFFICE

**23373**

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